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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David Aston, Ph.D., J.D.
Peters, Verny, Jones & Schmitt LLP
425 Sherman Ave
Suite 230
Palo Alto, CA 94306-1827

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,788	MAHAN ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,7,13 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2,4,7,13* is/are rejected.

7)☐ Claim(s) *20,2,4,7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 2,4,7,13 and 20 have been amended and are under consideration. All other claims have been canceled.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 30,2004 has been entered.

Allowable Subject Matter

2. The previously indicated allowable subject matter in claim 13 is herein withdrawn in light of new grounds of rejection based partially on the broadened scope of the claim.

3. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

1. Applicant's arguments with respect to claims 13, 2,4, and 7 have been considered but are moot in view of the new ground(s) of rejection.

2. All prior art rejections are herein withdrawn in light of new grounds of rejection set forth below.

Claim Objections

3. Claims 2,4 and 7 are objected to because of the following informalities: Claims 2, 4 and 7 depend from a later presented claim and should depend from a prior claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 13, 2, 4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Torreblanca et al(1996).

Torreblanca et al disclose a composition that is immunogenic, the composition comprising:

A diluent (a species of the instantly claimed excipients), specifically nutrient broth with added NaCl or E-medium without citrate together with glucose or lactose (see page 16, col. 2, paragraph 2)

(The instant Specification defines excipient to include diluents . "Preferably, the compositions comprise a pharmaceutically acceptable excipient. A pharmaceutically acceptable excipient is a relatively inert substance that facilitates administration of a pharmacologically effective substance. For example, an excipient can give form or consistency to the vaccine composition, or act as a diluent.")

a DNA Adenine Methylase Salmonella typhimurium mutant that comprises a first heterologous nucleotide sequence, the heterologous nucleotide sequence being a coding sequence for an antigen of a microorganism which causes an enteric infection, specifically E.coli. The E.coli antigen encoded by the heterogeneous nucleotide sequence is DNA Adenine Methylase of E.coli (see title, abstract, page 20, col. 1, paragraph 2 "Complementation of dam mutations of S.typhimurium by the E.coli dam+ gene)),

wherein the altered DAM activity is through the presence of a second heterologous nucleotide sequence, (see Table 1, for example strains are produced through the insertion of a plasmid carried heterologous nucleotide sequence that encodes antibiotic resistance Tn10dTet rpsL1 strains), and

wherein the first heterologous nucleotide sequence is operatively inserted into a first plasmid and the second heterologous nucleotide sequence is operatively inserted into a second plasmid (see page 16, col. 1, paragraph 4, "plasmids and transposons"; page 17, Table 1; page 18, col. 2, "the recipient of plasmids"; page 21, Table 2; page 24, col. 1, paragraphs 1-4)

The presence of a second mutations aids in preventing reversion of the strain to wild type, specifically a combination of dam together with recD, recF or recJ (see page 20, col. 1, paragraph 4).

The reference anticipates the instantly claimed invention as newly amended to include antigens of enteric infection.

6. Claims 13, 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Kleanthous et al (US Pat. 6,585,975, priority date April 30, 1998) as evidenced by Torreblanca et al(1996).

Kleanthous et al disclose immunogenic compositions that comprises:

An excipient (see col. 5, lines 46-67, col. 6, lines 1-67, col. 7, lines 1-8), in combination with

An inactivated (see col. 2, lines 51-60; especially line 58 "genes") DNA Adenine Methylase Salmonella typhimurium attenuated (see col. 1, line 59-60, col. 3, lines 13-19; col. 3, lines 60-64) mutant (see col. 3, lines 6-7 and evidence provided by Torreblanca et al , 1996), wherein the attenuated Salmonella typhimurium also comprises

a first heterologous nucleotide sequence, the heterologous nucleotide sequence being a coding sequence for an antigen of a microorganism that is a pathogenic bacterium and causes gastric infection , specifically *Helicobacter pylori, H.felis, H. mustelae,* and *H.heilmanii* (see col. 1, lines 11-30, col. 4, lines 1-35), fused to a second heterologous nucleic acid encoding an antigen from an enteric pathogen (see col. 5, lines 46-67).

wherein the altered DAM activity is inactivated, and the first heterologous nucleotide sequence is operatively inserted into a first plasmid (see col. 4, lines 3-10).

The presence of a second mutations aids in preventing reversion of the strain to wild type, specifically a combination of dam together (col. 1, lines 58-67).

The reference inherently anticipates the instantly claimed invention as newly amended to include antigens of pathogenic bacteria.

7. Claims 13, 2, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bandyopadhyay et al (1994).

Bandyopadhyay et al disclose a composition that is immunogenic, the composition comprising:

A diluent (a species of the instantly claimed excipients), specifically minimal media containing 1% casamino acids (see page 69, col. 2, Fig. 3 legend narrative)

(The instant Specification defines excipient to include diluents . "Preferably, the compositions comprise a pharmaceutically acceptable excipient. A pharmaceutically acceptable excipient is a relatively inert substance that facilitates administration of a pharmacologically effective substance. For example, an excipient can give form or consistency to the vaccine composition, or act as a diluent.")

a DNA Adenine Methylase E,.coli mutant (E.coli GW3810) that comprises a first heterologous nucleotide sequence, the heterologous nucleotide sequence being a coding sequence for an antigen of Vibrio cholera, a pathogen that causes an enteric infection. The Vibrio cholera antigen encoded by the heterogeneous nucleotide sequence is DNA Adenine Methylase antigen,

wherein the altered DAM activity is through the presence of a second heterologous nucleotide sequence, (see page 68, col. 1, paragraph 3 "GW3810 (JM103 dam::Tn9) , and over expression of the first heterologous nucleotide sequence which evidences DAM activity,

wherein the first heterologous nucleotide sequence is operatively inserted into a first plasmid (see Figure 1, page 68, plasmid encoding Vibrio cholera Dam methylase and col. 2, paragraph 1).

The reference anticipates the instantly claimed invention directed to dam mutant strains that express a Vibrio cholera heterologous coding sequence of an antigen, specific Dam methyltransferase.

8. Claims 13, 2, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Collier et al (US Pat. 5,451,519).

Collier et al (US Pat. 5,451,519) disclose a composition that is immunogenic, the composition comprising:

A diluent (a species of the instantly claimed excipients, definition provided in the instant Specification), specifically liquid media in 2YT broth (see col. 20, line 5; col. 20, lines 55-57), (The instant Specification defines excipient to include diluents . "Preferably, the compositions comprise a pharmaceutically acceptable excipient. A pharmaceutically acceptable excipient is a relatively inert substance that facilitates administration of a pharmacologically effective substance. For example, an excipient can give form or consistency to the vaccine composition, or act as a diluent.")

a DNA Adenine Methylase E,.coli mutant (E.coli strain 3055, see Example 3, col. 19, and Example 4, col. 20) that

comprises a first heterologous nucleotide sequence, the heterologous nucleotide sequence being a coding sequence for a different strain of E.coli's antigen, specifically EcoR1 endonuclease or EcoR1 methyltransferase (col. 20, lines 38-64) or B-galactosidase (see col. 19, lines 49-51), (E.coli being a microorganism which causes enteric infection.)

wherein the first heterologous nucleotide sequence is operatively inserted into a first plasmid (see Example 4, col. 20, "pGUBC-2080" and "pR113").

The reference anticipates the instantly claimed invention directed to dam mutant strains that express an heterologous E.coli coding sequence of an antigen, that comprises a diluent excipient.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Anderson et al (US Pat. 4,798,791) is cited to show a Dam negative mutant strain of E.coli (see col. 5, lines 9-31) that expresses a heterologous nucleotide sequence encoding a heterologous protein (see claim 2).

11. Bassing et al (1992) shows a mutant E.coli RR1 strains transformed with H. influenza heterologous nucleotide sequence which encodes a methyltransferase, wherein the methyltransferase was "overproduced" in the E.coli RRI host cell (see abstract and col. 1, page 84, "related to M.Dam (GATC)".

12. Heithoff, Douglas Matthew (1999, Dissertation abstract) is cited to show Salmonella typhimurium Dam mutant strain that totally lack Dam activity.

13. Reynoso et al (US Pat. 5,827,515) is cited to show a recombinant E.coli dam negative strain (GM2163) transformed with a heterologous antigen from a microorganism that causes enteric infection, specific Bacillus thuringiensis sporulation gene, the recombinant cells were

combined with a diluent referred to as SOC medium (see detailed description paragraphs 75-93, Example 1, col. 11 and following).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
November 02, 2004

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600